

## **Remarks/Arguments**

Reconsideration and allowance of this application and the claims therein are respectfully requested. Upon entry of the foregoing amendment, claims 3 and 23 have been canceled.

Claims 1, 2, 4-22, and 24-38 are pending, with 39-73 having been withdrawn, and claims 1, 20, 22, 25-27, 31, and 32 amended herein.

Support for the amendments to the claims can be found throughout the specification and in the claims as originally filed. In particular, support for the amendment to claim 1 can be found in the specification at [0015] and in original claim 3. Support for the amendment to claim 20 can be found in paragraph [0070]. Support for the amendment to claim 25 can be found in claim 24 as originally filed. The amendments to claims 26, 27, 31, and 32 are supported by the claims as originally filed. The amendments are believed to introduce no new matter. Entry of the amendments and new claims is respectfully requested.

### **1. Restriction/Election**

The Examiner's consideration of Applicants' election is acknowledged with thanks.

### **2. Rejections**

#### **A. 35 U.S.C. § 101**

The Office Action rejects claims 1-38 under 35 U.S.C. § 101 for alleged lack of either a specific asserted utility or a well-established utility. Applicants respectfully submit that this rejection should be withdrawn because the Office Action does not establish a *prima facie* case of lack of utility.

Establishment of a *prima facie* case of lack of utility requires consideration of all asserted utilities in an application. "The *prima facie* showing must contain the following elements: (A) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for

the claimed invention is neither both specific and substantial nor well-established. . . ." M.P.E.P. 2107.02(IV). Furthermore, it is well-established that "if an applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established." M.P.E.P. 2107.02(I).

Because only one credible assertion of utility is necessary, when establishing a *prima facie* case an Office Action should include consideration of all asserted utilities. "Each claim (i.e. each 'invention'), therefore, must be evaluated on its own merits for compliance with all statutory requirements." M.P.E.P. 2107.02. Applicants respectfully submit that the Office Action does not include consideration of all utilities asserted in the application. For instance, claim 2 states that the claimed polynucleotide "regulates transcription of  $\beta$ -galactosidase in a bacterial host cell." The increased expression of  $\beta$ -galactosidase under the transcriptional control of SEQ ID NO:7 is shown in Table 9 and discussed in Example 9.  $\beta$ -galactosidase is recognized as an enzyme that cleaves lactose into galactose and glucose.

No proper *prima facie* showing of lack of utility has been made in the Office Action. Because a proper *prima facie* showing has not been made, the rejection should be withdrawn and the claims allowed.

#### **B. 35 U.S.C. § 112**

The Office Action rejects claims 1-38 under 35 U.S.C. § 112, first paragraph, for alleged failure to show a person skilled in the art how to make and use the invention. The Office Action states that the rejection is based on the alleged lack of "either a specific asserted utility or a well established utility for the reasons set forth [in the rejection based on 35 U.S.C. § 101]. . . ."

This rejection is based on the 35 U.S.C. § 101 rejection appearing in this Office Action. That rejection should be withdrawn for failure to establish a *prima facie* case of lack of utility. Because the rejection under § 101 fails, this rejection must necessarily fail as well.

The Office Action also rejects claims 1-38 under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the written description requirement. That rejection is traversed. There is clearly written description for the nucleotide sequence set forth in SEQ ID NO:7. The claimed isolated polynucleotide is described functionally and structurally by sequence identifiers, stringent hybridization conditions (as that term is defined in the specification) and percent identity. A person of skill in the art would not expect substantial variation among species within the scope of the claims, because the hybridization conditions and percent identity set forth in the claim will yield structurally similar polynucleotides. A representative species is disclosed, the claims are drawn to a genus that hybridizes with or has sequence identity to a given sequence, and activity is adequately described.

The Examiner's attention is respectfully drawn to Example 14 of the "Revised Interim Written Description Guidelines Training Materials." The claims in the instant application closely reflect those of the Example. The polynucleotides of the instant invention have promoter activity, and they have at least 90% identity to a reference structure. The Example does not require that specific insertions, deletions, or other changes be set forth. Similarity of the claims of the instant application to the Example demonstrates the claims' compliance with the written description requirement.

The Office Action rejects claims 20-21, and 24-26 under 35 U.S.C. § 112, second paragraph. That rejection has been rendered moot by amendment of claims 20, 21, and 26, and cancellation of claim 24.

Applicants respectfully submit that the requirements of 35 U.S.C. § 112 have been satisfied by all pending claims of the application as amended herein. Withdrawal of the rejections and allowance of the pending claims is respectfully requested.

**C. 35 U.S.C. § 102**

The Office Action rejects claims 22 and 24 under 35 U.S.C. § 102 as allegedly anticipated by Vyostskaia, et al., Acc. No. AC000132, 1997. That rejection is rendered moot by the amendment of claim 22 and the cancellation of claim 24.

**3. Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all of the outstanding objections and rejections, then allow all of the outstanding claims as amended. Applicants believe that a full and complete reply has been made to the Office Action and that the application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite allowance of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,



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